METHODS

Intraaortic Balloon Pump Insertion: A Randomized Study Comparing Percutaneous and Surgical Techniques

MARK J. GOLDBERG, MD, FACC, MELVYN RUBENFIRE, MD, FACC,

ADRIAN KANTROWITZ, MD, FACC, GARY GOODMAN, MD, FACC, PAUL S. FREED, MS,

LEONARD HALLEN, MD, PAULA REIMANN, RN

Detroit, Michigan

To compare the percutaneous and surgical techniques of intraaortic balloon pump insertion, 101 patients referred for this procedure were randomly assigned to either percutaneous or surgical insertion. Insertion using the designated technique was successful in 45 (88%) of 51 patients with percutaneous insertion and 48 (96%) of 50 patients with surgical insertion (difference not statistically significant). The time from the beginning of the insertion procedure to the initiation of counterpulsation was 13 ± 8 minutes for the percutaneous technique versus 31 ± 16 minutes for the surgical technique (p < 0.001).

In the percutaneous group, 10 patients required Fogarty thrombectomy after balloon pump removal, and 1 patient developed severe leg ischemia requiring immediate termination of balloon pump support. In the surgical group, one patient developed leg ischemia requiring surgical intervention, three patients developed sepsis with bacteremia (including one patient who required vein patch repair of the femoral artery), one patient developed a wound infection requiring debridement and one patient had a cerebral embolus. Aortic dissection, aortoiliac perforation or amputation did not occur in either group. Major vascular complications occurred in 11 patients (22%) with percutaneous insertion versus 2 patients (4%) with surgical insertion (p < 0.05).

It is concluded that although the percutaneous technique for intraaortic balloon pump insertion is faster than the surgical technique and is technically easy, it is associated with a higher incidence of vascular complications.

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Since its initial clinical use in 1967, intraaortic balloon pump counterpulsation has been employed with increasing frequency in the treatment of patients with cardiogenic shock, postoperative left ventricular failure, unstable angina and postinfarction angina (1–11). For many years, balloon pump catheter insertion required surgical exposure of the femoral artery and removal required a second surgical procedure (1). Introduction of the percutaneous technique for balloon pump catheter insertion in 1979 (12,13) allowed physicians experienced in the Seldinger method of catheterization to perform balloon pump insertion and removal with greater speed.

Initial studies (12–14) also suggested that the percutaneous technique was associated with a lower complication rate. More recent nonrandomized studies (5,15–18) have reported the percutaneous complication rate to be equal to or higher than the surgical complication rate. We have performed a randomized study to compare the percutaneous and surgical techniques in terms of complications and success rate and speed of insertion.

Methods

Study patients. From August 1981 through June 1983, 194 patients underwent 221 intraaortic balloon pump insertion procedures at Sinai Hospital of Detroit. One hundred one of these patients participated in our randomized study.

Patients were eligible for entry into the study if intraaortic balloon pump insertion was clinically indicated and if 1) a palpable femoral artery pulse was present, 2) there was no history of previous aortofemoral or aortoiliac reconstructive surgery, 3) there was no history of previous insertion or attempted insertion of an intraaortic balloon pump, and 4)

appropriate informed consent was given. Patients requiring balloon pump support immediately after coronary angiography were excluded because a catheter was already in place in the femoral artery and patients requiring balloon pump insertion in the operating room after cardiac surgery were excluded because a surgeon was already available for the insertion procedure.

Study protocol. The study comprised a total of 101 patients. A computer-generated random sequence was utilized to exclude selection bias and the study patients were divided into three groups. Thirty-four patients were randomly assigned to percutaneous insertion by a staff cardiologist and 17 patients were assigned to percutaneous insertion by a staff surgeon, giving a total of 51 patients assigned to percutaneous insertion. Fifty patients were assigned to surgical insertion by a staff surgeon. The study protocol was approved by the Sinai Hospital of Detroit Medical Research Committee on January 30, 1981.

After the patients agreed to participate in the study and gave informed consent, a sealed envelope was opened and the randomization category was determined. Patient age, sex, height (inches) and weight (pounds) were recorded, as well as the indication for balloon pump insertion. Hemoglobin and hematocrit values and Doppler ankle/arm systolic pressure index values were determined before balloon pump insertion. For measurement of Doppler ankle/arm systolic pressure index (ankle/arm index), Doppler ankle systolic pressure was measured using a pneumatic cuff with an 8 × 40 cm inflatable bladder. Arm systolic pressure was measured either indirectly using a sphygmomanometer for brachial artery pressure or directly with intraarterial pressure recording through a radial artery catheter (when available). Ankle/arm index was calculated as the ankle systolic pressure divided by the arm systolic pressure. Values were determined for both lower limbs.

Balloon pump insertion. Balloon pump insertion was then performed using the method designated by the randomization process. Percutaneous balloon pump insertion was performed using Datascope non-wire–guided catheters (Percor) during the initial phase of the study (5 patients); Datascope wire-guided catheters (Percor-DL, Percor-DLII) then became available and were used subsequently (46 patients). An 11 inch (27.9 cm) 12F (Percor-DLII) or 12.5F (Percor, Percor-DL) dilator-sheath combination was employed. Fluoroscopy was used at the discretion of the physician performing insertion. Surgical insertion was performed using either a standard balloon pump catheter (Datascope) or one of the percutaneous balloon pump catheters described, with the balloon pump catheter inserted using an end to side Dacron graft to the femoral artery (a transverse arteriotomy without an end to side graft was used in one case).

Balloon pump insertion was considered successful if, using the designated technique, the balloon catheter was successfully inserted in the femoral artery initially chosen for insertion. Whether or not to abandon the initially chosen femoral artery or the designated technique was decided by the inserting physician in the interest of optimal patient care. The insertion time, measured in minutes from the beginning of the insertion procedure to the initiation of counterpulsation, was recorded in each case of successful insertion. The time from request for balloon pump insertion to initiation of counterpulsation, also measured in minutes, was recorded in each case of nonelective successful insertion.

After successful balloon pump insertion, full dose intravenous heparin was administered to maintain the partial thromboplastin time at 1.5 to 2.5 times the control time. Patients undergoing cardiac or general surgery did not receive heparin after surgery; most of these patients received low molecular weight dextran (20 ml/h) after surgery until the balloon pump was removed. Cephalothin (1 g intravenously every 6 hours) was administered while the balloon pump was in place as long as there was no history of allergy to penicillin.

Balloon pump removal. A balloon pump inserted using the percutaneous technique was removed percutaneously in all but three cases; with continuous digital pressure applied over the femoral artery for 20 to 30 minutes to obtain hemostasis. Protamine sulfate (50 mg) was administered intravenously immediately before removal of the percutaneous balloon pump in the majority of patients receiving heparin at that time. In three cases, a balloon pump catheter inserted percutaneously was surgically removed, followed by Fogarty thrombectomy. In these cases, the presence of thrombus in the femoral or iliac artery had been suspected before balloon pump removal.

Balloon pumps inserted surgically were removed with a second surgical procedure; at the time of removal, a Fogarty embolectomy catheter was advanced from the femoral arteriotomy site proximally to the abdominal aorta and distally down the branches of the femoral artery to retrieve any thrombotic material before oversewing of the prosthetic graft. The presence or absence of thrombus during removal of each surgically inserted balloon pump was recorded.

Patient follow-up. Hemoglobin and hematocrit values were measured 24 hours after balloon pump insertion, then daily or more often as clinically warranted. Ankle/arm index values were measured 12 to 24 hours after balloon pump insertion. Measurement of postinsertion ankle/arm index was performed with the balloon pump turned off for the brief period of time necessary for pressure measurement, using direct radial artery pressure for arm systolic pressure.

Details of the hospital course for each patient were recorded, including 1) duration of balloon pump support (days); 2) presence of hemodynamic criteria for cardiogenic shock at any time during balloon pump support (including post-cardiac surgical low output syndrome); 3) therapy with an inotropic agent at any time during balloon pump support;

Table 1. Study Population

	Percutaneous (n = 51)	Surgical (n = 50)	p Value
Age (yr)	62 ± 11	61 ± 9	NS
Men (%)	65	70	NS
Women (%)	35	30	NS
Height (inches)	66 ± 5	66 ± 10	NS
Weight (lb)	165 ± 28	168 ± 39	NS

4) cardiac surgery after balloon pump insertion, and 5) patient death during balloon pump support. Complications of balloon pump insertion were noted, as was the administration of blood transfusion at any time during balloon pump support (excluding transfusion after cardiac or general surgery).

Statistical analysis. Data for patient age, height and weight, hemoglobin and hematocrit values, ankle/arm index values, duration of balloon pump support, insertion time and time from request to initiation of counterpulsation are presented as mean values ± 1 SD. Hemoglobin and hematocrit values obtained after cardiac or general surgery or after blood transfusion were excluded from analysis. Ankle/arm index values greater than 1.00 were considered to be 1.00 for the purpose of statistical analysis. Postinsertion ankle/arm index values were included only for patients in whom balloon pump insertion was considered successful and in whom the balloon pump catheter was still in place at the time of the post-insertion measurements. Comparisons were made between percutaneous insertion and surgical insertion groups for mean values and between cardiologists and surgeons for mean percutaneous insertion time using the nonpaired t test. Comparisons were made between preinsertion and postinsertion ankle/arm index data using the paired Student's t test. Comparisons were made between the percutaneous and surgical groups in terms of ratio of men to women, frequency of various indications for balloon pump insertion, frequency of various hospital course characteristics, insertion success rate, vascular complication rate and incidence of blood transfusion, using chi-square analysis. Significance of data was determined at the level of probability (p) less than 0.05.

Results

The percutaneous and surgical groups were similar in terms of mean patient age, height and weight and sex ratio (Table 1). The two groups also had a similar distribution of indications for balloon pump insertion (Table 2). Unstable or postinfarction angina was the primary indication for balloon pump insertion for the majority of patients in both groups.

There was no difference between the percutaneous and surgical groups in terms of duration of balloon pump support, percentage of patients manifesting hemodynamic criteria for cardiogenic shock, therapy with inotropic agents, requirement for subsequent cardiac surgery or expiration during balloon pump support (Table 3).

Percutaneous Technique

Success rate. Of the 51 patients in the percutaneous group, 46 had percutaneous insertion attempted using a wire-guided percutaneous catheter and 5 had percutaneous insertion attempted using a non-wire-guided catheter. Percutaneous insertion was successful in 41 (89%) of the 46 cases involving a wire-guided catheter and in 4 (80%) of the 5 cases in which a nonwire-guided catheter was used (p = NS). Overall, percutaneous insertion was successful in 88% of patients in the percutaneous group. Fluoroscopy was used for 21 (46%) of the 46 patients with a wire-guided percutaneous insertion procedure; insertion was successful in 19 (90%) of the 21 cases in which fluoroscopy was used, and was successful in 22 (88%) of the 25 cases in which fluoroscopy was not used (p = NS).

Unsuccessful cases. Percutaneous insertion was unsuccessful in six cases. Failure to advance the balloon catheter was presumably related to severe aortoiliac atherosclerosis in two cases; surgical insertion was subsequently attempted through the same femoral artery in one of these cases, without success. Percutaneous insertion was unsuccessful in two

Table 2. Indications for Intraaortic Balloon Pump Insertion

	Percutaneous (n = 51)	Surgical (n = 50)	p Value
MI with cardiogenic shock (%)	18	16	NS
Unstable angina (%)	31	20	NS
Post-MI angina (%)	20	34	NS
Preoperative support (%)	18	18	NS
MI with mitral regurgitation (%)	6	2	NS
MI with ventricular septal defect (%)	2	4	NS
Ventricular arrhythmia (%)	2	2	NS
Other (%)	4	4	NS

MI = myocardial infarction.

Table 3. Hospital Course

	Percutaneous (n = 51)	Surgical (n = 50)	p Value
Duration of IABP (days)	3.8 ± 2.7	4.4 ± 2.6	NS
Criteria for cardiogenic shock (%)	61	66	NS
Inotropic agents (%)	61	77	NS
Cardiac surgery (%)	43	52	NS
Expired during IABP support (%)	22	12	NS

IABP = intraaortic balloon pump.

cases because of inability to advance the guide wire initially and in another case because of inability to advance the introducer sheath over the guide wire past the aortic bifurcation and in an additional case because of inability to advance the balloon pump catheter through the indwelling introducer sheath. A percutaneous balloon pump catheter was successfully inserted through the same femoral artery at a later date in this last case. Fluoroscopy was utilized in two of the six unsuccessful cases.

The percutaneous insertion success rate was slightly higher for cardiologists (91%) than for surgeons (82%); this difference was not statistically significant.

Insertion time. The mean insertion time or the time from the beginning of the insertion procedure to counterpulsation was 13 ± 8 minutes for percutaneous insertions.

The percutaneous insertion times for cardiologists (12 ± 8 minutes) and surgeons (13 ± 8 minutes) did not differ significantly. The mean time from request for balloon pump insertion to initiation of counterpulsation was 134 ± 51 minutes in patients with percutaneous insertion.

Major complications. Ten patients in the percutaneous group developed lower limb ischemia requiring Fogarty thrombectomy after balloon pump removal (Table 4). Thrombectomy followed percutaneous balloon pump catheter removal in seven patients and surgical removal in three patients. In one of these patients it was discovered at the time of thrombectomy that the balloon pump catheter had been inadvertently inserted into the superficial femoral artery instead of the common femoral artery. The mean duration of balloon pump support before thrombectomy in the

Table 4. Major Complications

Complication	Percutaneous		Surgical		
	No. of Patients	%	No. of Patients	%	p Value
Lower limb ischemia requiring surgical intervention	10	20	1	2	
Severe lower limb ischemia requiring immediate IABP removal	1	2	0	—	
Sepsis with bacteremia requiring vein patch repair of femoral artery	0	—	1	2	
Sepsis with bacteremia not requiring vein patch repair of femoral artery	0	—	2	4	
Wound infection requiring debridement	0	—	1	2	
Cerebral embolus	0	—	1	2	
Total major complications	11	22	6	12	NS
Total major vascular complications	11	22	2	4	<0.05

IABP = intraaortic balloon pump.

10 patients was 3.5 ± 2.1 days. This did not differ significantly from the duration of balloon pump support (3.7 ± 2.6 days) in the remaining 35 patients in the percutaneous group who underwent successful insertion and did not require thrombectomy. One patient in the percutaneous group developed severe lower limb ischemia almost immediately after balloon pump insertion and required immediate balloon pump removal and termination of balloon pump support.

Minor complications. Four patients (8%) in the percutaneous group were found to have malposition of the balloon pump catheter on chest X-ray film after insertion, with the tip of the catheter either too high (in the left common carotid artery) or too low (in the lower thoracic aorta or abdominal aorta).
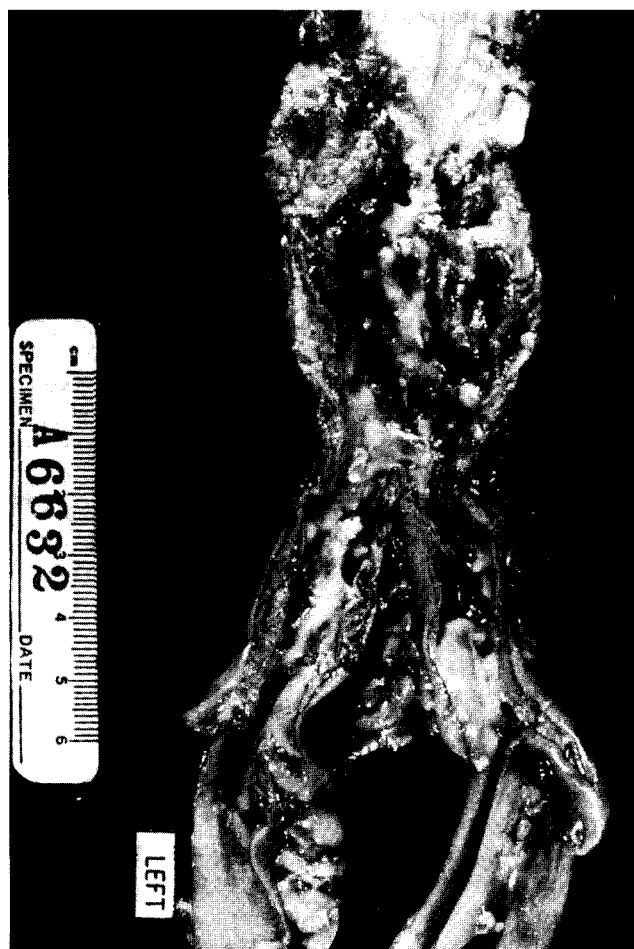
Surgical Technique

Success rate. Of the 50 patients in the surgical group (Fig. 1), 43 had surgical insertion attempted using a surgical balloon pump catheter initially; insertion of this catheter was successful in 33 patients and unsuccessful in 10. Surgical insertion using a percutaneous catheter was then attempted in these 10 patients and was successful in 8 of them and unsuccessful in 2. Unsuccessful insertion was related to severe aortoiliac atherosclerosis in both cases (Fig. 2). Surgical insertion was attempted with a percutaneous catheter initially in seven patients in the surgical group and was successful in every patient. Overall, surgical insertion using either a surgical catheter or a percutaneous catheter was successful in 96% of patients in the surgical group.

Insertion time. The mean insertion time for surgical insertions was 31 ± 16 minutes, whereas the mean time from request to initiation of counterpulsation was 163 ± 66 minutes.
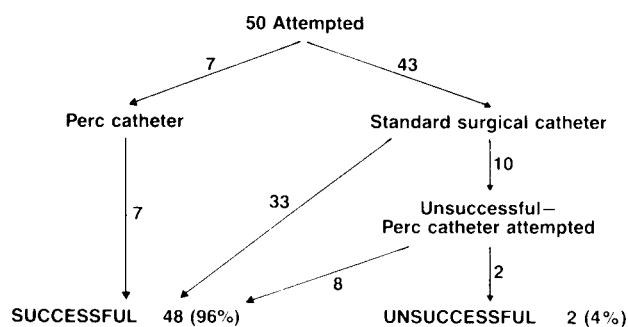
Major complications. One patient in the surgical group developed lower limb ischemia requiring a repeat Fogarty thrombectomy procedure as well as anterior compartment fasciotomy after the routine surgical balloon pump removal procedure. Thrombus was retrieved with a Fogarty catheter

Figure 1. Results of intraaortic balloon pump insertion using the surgical technique. Surgical insertion was attempted using either a standard surgical or percutaneous (Perc) catheter.

during routine surgical balloon pump removal in nine additional patients in the surgical group. Because this occurred as part of the routine removal procedure, these patients were not considered to have had a vascular complication. Three patients in the surgical group developed sepsis with bacteremia, including one patient who had vein patch repair of the femoral artery and was considered to have had a vascular complication. Bacteremia occurred, respectively, on day 3, day 8 and day 9, of balloon pump support in these patients. All three patients underwent cardiac surgery before the development of clinical evidence of sepsis. Sepsis and bacteremia were probably related to balloon pump insertion in one patient, in whom the organism detected in blood cultures was also detected in the balloon pump wound and on the tip of the balloon pump catheter. In the other two patients,

Figure 2. Autopsy specimen from one of the two patients in whom an intraaortic balloon pump could not be successfully inserted using the surgical technique. Severe atherosclerosis involving the abdominal aorta and iliac arteries is seen. Insertion was attempted in the left femoral artery, using first a standard surgical balloon pump catheter and then a wire-guided percutaneous catheter with fluoroscopy. Insertion in the right femoral artery was not attempted.

the organism detected in blood cultures was not detected in the balloon pump wound or on the tip of the balloon pump catheter, and sepsis and bacteremia can be considered only as possible balloon pump complications. One patient in the surgical group developed a wound infection that required debridement as well as antibiotic therapy. Another patient in the surgical group developed disorientation and left hand weakness during balloon pump support, 6 days after insertion, and it was believed that a small cerebral embolic event had probably occurred. This patient had recent myocardial infarction with left ventricular aneurysm, and therefore the cerebral embolic event can be considered only a possible balloon pump complication.

Minor complications. Five patients (10%) in the surgical group were found to have catheter malposition on chest X-ray film. Six patients (12%) had wound infection not requiring debridement; one of these patients also had a lymphatic fistula and another had a seroma. Excessive bleeding or hematoma, or both, occurred in five patients (10%). Cellulitis developed in one patient, and balloon leak requiring balloon pump catheter replacement occurred in one patient.

Comparisons

Success rate. The overall surgical insertion success rate (96%) was slightly higher than that for percutaneous insertion (88%), but this difference was not statistically significant.

Insertion time. The mean insertion time was significantly lower for the percutaneous group (13 ± 8 minutes) than for the surgical group (31 ± 16 minutes) (p < 0.001). The time from request to initiation of counterpulsation was also significantly lower for percutaneous (134 ± 51 minutes) than for surgical insertions (163 ± 66 minutes) (p < 0.05).

Vascular complications. No patient in either group had clinically detectable aortic dissection, aortoiliac perforation, lower limb amputation or pseudoaneurysm. Autopsy examination was performed on six patients (three percutaneous and three surgical) who died during hospitalization and no evidence of clinically unsuspected aortic dissection was found.

The vascular complication rate was 22% for the percutaneous group and 4% for the surgical group (p < 0.05). The percutaneous vascular complication rate was also higher than the corresponding surgical rate in both female (28 versus 13%) and male (18 versus 0%) subgroups, but these differences were not statistically significant. The vascular complication rate for women was higher than that for men in both the percutaneous and surgical groups; these differences were also not significant.

Ankle/arm systolic pressure index. The percutaneous and surgical groups did not differ significantly in terms of preinsertion or postinsertion Doppler ankle/arm index on the side of balloon pump insertion (Table 5). The preinsertion to postinsertion difference in ankle/arm index was greater for the surgical group, but this difference was not statistically significant. The postinsertion ankle/arm index was significantly lower than the preinsertion ankle/arm index in both the percutaneous and surgical groups.

Bleeding. The mean decrease in hemoglobin from before to 24 hours after insertion was 0.8 ± 0.9 g/deciliter for percutaneous and 1.6 ± 1.1 g/dl for surgical insertions (p < 0.05). The mean decrease in hematocrit from before to 24 hours after insertion was 2.3 ± 3.0% for percutaneous and 5.2 ± 3.3% for surgical patients (p < 0.005). Blood transfusion (excluding that after cardiac or general surgery) was required for 18 (36%) of 50 patients in the surgical group compared with 4 (8%) of 51 patients in the percutaneous group (p < 0.01).

Discussion

Previous studies. Major complication rates between 9 and 36% have been reported in various studies (2,8,19–23) using the standard surgical technique for balloon pump insertion. The initial encouraging reports of percutaneous balloon pump insertion indicated major complication rates between 4 and 8% (12,13), whereas subsequent studies reported

Table 5. Ankle/Arm Systolic Pressure Index Data

	Percutaneous (n = 51)	Surgical (n = 50)	p Value
AAI			
Preinsert	0.89 ± 0.15 (43)	0.95 ± 0.10 (46)	NS
Postinsert	0.76 ± 0.30 (35)	0.71 ± 0.25 (44)	NS
ΔAAI	0.15 ± 0.25 (31)	0.21 ± 0.22 (41)	NS

AAI = ankle/arm index on the side of balloon pump insertion; ΔAAI = difference between preinsertion and postinsertion ankle/arm index on the side of balloon pump insertion. Numbers in parentheses represent numbers of patients with applicable data.

rates between 7 and 15% (24–30). A number of nonrandomized studies (5,14–18) have compared the percutaneous and surgical techniques. Bemis et al. (14) found a lower complication rate with the percutaneous technique (5 versus 19% for surgical insertion). In a study by Alcan et al. (15), wire-guided percutaneous insertion and surgical insertion were associated with almost identical major complication rates (15.2 and 15.6%, respectively). Similarly, percutaneous and surgical major complication rates did not differ significantly in a study by Shahian et al. (17) (17.4 and 12.2%, respectively). Percutaneous insertion was associated with a higher major complication rate (9.9 versus 3.5% for surgical insertion) in a study by Pennington et al. (5) and was associated with a higher vascular complication rate (27 versus 14% for surgical insertion) in a report by Gottlieb et al. (18).

Comparing balloon pump insertion complication rates from different studies is difficult. Complication rates depend on the physician's level of skill and experience, how complications are defined and whether data are obtained prospectively or retrospectively. The relative frequencies of various indications for balloon pump insertion also influence complication rates; patients with cardiogenic shock have a higher complication rate than do patients undergoing balloon pump insertion before elective coronary artery bypass graft surgery (20). Assessment of complication rates is also difficult because complications associated with unsuccessful balloon pump insertion have not always been included in reports, which leads to an underestimation of true complication rates. Also, some patients die soon after balloon pump insertion and before complications can be recognized clinically (22).

Vascular complications. Our randomized comparison of the percutaneous and surgical techniques of intraaortic balloon pump insertion indicates that percutaneous insertion is associated with a higher incidence of vascular complications, particularly with the need for Fogarty thrombectomy after balloon pump removal. There are a number of possible explanations for this difference in vascular complication rates. Greater trauma to the femoral artery could possibly occur with the percutaneous technique. The balloon pump catheter is occasionally inserted inadvertently into the superficial femoral artery instead of the common femoral artery with the percutaneous technique, predisposing the patient to thrombus development because of the smaller arterial lumen size. This problem occurred in only one of the percutaneous cases requiring Fogarty thrombectomy after balloon pump removal. The percutaneous technique, using a wire-guided catheter, could make possible successful balloon pump insertion in some patients with severe aortoiliac occlusive disease in whom surgical insertion with a standard balloon pump catheter would not be possible, predisposing to thrombus development in the iliac or femoral artery. This possibility does not appear to explain the difference in vas-

cular complication rates, because the surgical insertion success rate in this study was so high.

Our finding that thrombus was retrieved from the femoral or iliac artery during routine balloon pump removal in nine additional patients with surgical insertion (who are not considered to have had a vascular complication) suggests that the percutaneous and surgical techniques have similar rates of thrombus development in the femoral or iliac artery. The preinsertion to postinsertion difference in ankle/arm index in the percutaneous group did not differ significantly from that in the surgical group, suggesting that there is no major difference in the degree of femoral artery obstruction between the two techniques. The fact that an attempt is made routinely to retrieve thrombotic material with a Fogarty embolectomy catheter during removal of a surgically inserted balloon pump catheter probably accounts for the difference in vascular complication rates between the two techniques.

The percutaneous balloon pump removal technique that we used in our investigation was the technique in general use when the study was done. A modified removal technique has evolved (13,24,29), involving manual compression of the femoral artery below the insertion site at the time of balloon pump catheter removal while a jet of blood is allowed to flush the artery for 1 to 2 seconds, followed by compression of the artery above the insertion site with Doppler monitoring of ankle arterial blood flow. This newer removal technique may reduce the incidence of percutaneous balloon pump lower limb ischemic complications, particularly ischemia secondary to embolism of thrombotic material from the common femoral artery to a more distal arterial segment of the lower limb at the time of balloon pump catheter removal. Most of the patients in the percutaneous group in our study who developed a lower limb ischemic complication requiring surgical intervention developed evidence of lower limb ischemia on physical examination and by monitoring of the Doppler ankle/arm index before balloon pump catheter removal. Therefore, we do not believe that the use of this newer removal technique in our study would have substantially altered the results. One patient in our study did develop evidence of lower limb ischemia only after percutaneous balloon pump catheter removal and subsequently underwent popliteal artery embolectomy. Use of the newer removal technique might have prevented the complication that occurred in this patient.

Previous studies have reported significantly higher balloon pump complication rates in women than in men, which were attributed to the smaller size of femoral arteries in women (17,18). In our study, vascular complication rates were higher in women in both the percutaneous and surgical groups, but this difference was not statistically significant.

Clinical implications. Although the percutaneous technique is associated with a higher vascular complication rate than is the surgical technique, the incidence of major infectious complications appears to be lower with percuta-

neous (no cases) than with surgical insertion (one definite case, one probable case and two possible cases). We also found less blood loss and a lower requirement for blood transfusion with the percutaneous technique, which could have important clinical implications.

The percutaneous technique is rapid and technically easy. Its shorter insertion time provides an important advantage in certain situations, such as cardiac catheterization laboratory emergencies and cardiopulmonary resuscitation. However, when the time from request for balloon pump insertion to initiation of counterpulsation is taken into account, the difference in speed between the two techniques becomes relatively less important in most clinical settings.

This study failed to demonstrate a significant difference in insertion success rate between the percutaneous and surgical techniques. The study also failed to show a relation between the use of fluoroscopy and successful insertion with the percutaneous technique. For the majority of patients undergoing balloon pump insertion, both the percutaneous and surgical techniques are efficacious, with or without fluoroscopy. Nevertheless, we believe that on occasion, especially in patients with severe atherosclerosis or tortuosity involving the aortoiliac segment, the percutaneous technique with fluoroscopy offers a greater chance of successful insertion than does either the percutaneous technique without fluoroscopy or the surgical technique. We also believe that the use of the percutaneous technique with fluoroscopy reduces the risk of aortic dissection or aortoiliac perforation, although we were unable to demonstrate this in our study (neither complication occurred).

Surgical removal of percutaneously inserted balloon pump catheters is not routinely indicated. Monitoring of the status of the lower limb circulation with physical examination and Doppler ankle/arm pressure index measurements will identify those patients who require Fogarty thrombectomy after percutaneous removal of a balloon pump catheter. Percutaneous removal is preferable because of its ease, convenience and probable lower risk of infection for patients who do not develop thrombus in the iliac or femoral artery.

Recent technical advances may lead to a decrease in percutaneous balloon pump vascular complication rates in the near future. Percutaneous balloon pump catheters are now available in the 10.5F size (wire-guided) and 8.5F size (nonwire-guided), and use of these smaller catheter sizes could reduce the incidence of thrombus development in the femoral or iliac artery. A 15 inch (38 cm) introducer sheath is also available; use of this longer sheath may increase the insertion success rate and may further decrease the already low incidence of aortic dissection and aortoiliac perforation, especially in patients with severe atherosclerosis or tortuosity.involving the aortoiliac segment (14).

Conclusion. The percutaneous and surgical techniques for intraaortic balloon pump insertion are associated with similar insertion success rates. Percutaneous insertion is

faster and easier than is surgical insertion. However, the percutaneous technique is associated with a higher incidence of vascular complications, particularly those requiring Fogarty thrombectomy after balloon pump removal. The fact that Fogarty thrombectomy is attempted routinely during removal of a surgically inserted balloon pump probably accounts for the difference in vascular complication rates between the two techniques. Lower limb circulation must be monitored carefully for signs of ischemia after percutaneous balloon pump insertion and after balloon pump removal. Monitoring should include both clinical observation and Doppler monitoring of arm and leg pressures.

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